

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

GLAXOSMITHKLINE PLC; PFIZER,	)	
INC.; ENCYSIVE	)	<b>C.A. No. 3:12-CV-01965-FLW-</b>
PHARMACEUTICALS, INC.;	)	<b>DEA</b>
Plaintiffs,	)	
MITSUBISHI CHEMICAL CORP.; and	)	
MITSUBISHI TANABE PHARMA	)	
CORP.,	)	
Involuntary Plaintiffs,	)	<b><i>Document Electronically Filed</i></b>
v.	)	
HIKMA PHARMACEUTICAL CO.,	)	
LTD.; and WEST-WARD	)	
PHARMACEUTICAL CORP.,	)	
Defendants.	)	

**PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW  
IN SUPPORT OF THE PLAINTIFFS' AND DEFENDANTS' JOINT  
MOTION TO SEAL AND REDACT THE TRIAL TRANSCRIPTS**

## **INTRODUCTION**

Pursuant to Local Civil Rule 5.3(c), Plaintiffs GlaxoSmithKline, Pfizer, and Encysive Pharmaceuticals (“Plaintiffs”) and Defendants Hikma Pharmaceutical and West-Ward Pharmaceutical, (“Defendants”), hereby submit Proposed Findings of Fact and Conclusions of Law in support of the parties’ Joint Motion to Seal the Trial Transcripts. Local Civil Rule 5.3(c) places the burden of proof on the moving party as to why a motion to seal or otherwise restrict public access should be granted. Specifically, it requires a showing of:

- (a) the nature of the materials or proceedings at issue;
- (b) the legitimate private or public interest which warrant the relief sought;
- (c) the clearly defined and serious injury that would result if the relief sought is not granted; and
- (d) why a less restrictive alternative to the relief sought is not available.

The Plaintiffs and Defendants seek to seal and redact certain portions of the Transcripts of the proceedings held before the Honorable Freda L. Wolfson on July 10-13, 2012 (collectively, the “Confidential Information”). Set forth below are the findings of fact and conclusions of law addressing each of the elements required by Local Civil Rule 5.3(c)(2). These findings of fact and conclusions of law support the granting of the Joint Motion to Seal and Redact the Trial Transcripts.

**I. The Nature of the Materials or Proceedings at Issue**

**A. Findings of Fact**

1. The Confidential Information consists of the Plaintiffs' and Defendants' sensitive confidential information relating to their respective New Drug Applications ("NDAs"), and proprietary information regarding business relationships and the formulation, development and manufacture of their drug products. The Plaintiffs and Defendants consider this information, and treat this information as, confidential and proprietary material that includes nonpublic trade secrets.

**B. Conclusions of Law**

2. There exists in civil cases a common law public right of access to judicial proceedings and records. Goldstein v. Forbes (In re Cendant Corp.), 260 F.3d 183, 192 (3d Cir. 2001) (citing Littlejohn v. BIC Corp., 851 F.2d 673, 677-78 (3d Cir. 1988)). The party seeking to seal any part of a judicial record bears the burden of demonstrating that "the material is the kind of information that courts will protect." Miller v. Indiana Hosp., 16 F.3d 549, 551 (3d Cir. 1994) (quoting Publicker Indus., Inc. v. Cohen, 733 F.2d 1059, 1071 (3d Cir. 1984)).

3. This Court has the power to seal where confidential information may be disclosed to the public. Fed. R. Civ. P. 26(c)(1)(G) allows the court to protect materials containing "trade secret[s] or other confidential research,

development, or commercial information[,]” upon motion by a party, to prevent harm to a litigant’s competitive standing in the marketplace. See Zenith Radio Corp. v. Matsushita Elec. Indus. Co., Ltd., 529 F. Supp. 866, 889-91 (E.D. Pa. 1981).

## **II. The Legitimate Private or Public Interest Which Warrant the Relief Sought**

### **A. Findings of Fact**

4. The Confidential Information sought to be sealed contains the parties’ sensitive confidential information relating to their NDAs and proprietary information regarding business relationships and the formulation, development and manufacture of the drug products that the parties consider to be confidential and proprietary.

5. The parties have an interest in not publicly disclosing this information and rely on such information to gain a competitive advantage in the pharmaceutical industry.

### **B. Conclusions of Law**

6. Courts have recognized that the presumption of public access is not absolute and may be rebutted. Republic of the Philippines v. Westinghouse Elec. Corp., 949 F.2d 653, 662 (3d Cir. 1991). “Every court has supervisory power over its own records and files, and access has been denied where court files might have become a vehicle for improper purposes.” Littlejohn, 851 F.2d at 678

(quoting Nixon v. Warner Commc'ns, Inc., 435 U.S. 589, 598 (1978)).

7. Courts may deny access to and seal a document when it encompasses business information that might harm a litigant's competitive standing. See Littlejohn, 851 F.2d at 678 (citations omitted).

8. The District of New Jersey has held that the inclusion of trade secrets and other confidential information in documents warrant the sealing of such documents. "A well-settled exception to the right of access is the 'protection of a party's interest in confidential commercial information, such as a trade secret, where there is a sufficient threat of irreparable harm.'" In re Gabapentin Patent Litig., 312 F. Supp. 2d 653, 664 (D.N.J. 2004) (citation omitted). "The presence of trade secrets or other confidential information weighs against public access and, accordingly, documents containing such information may be protected from disclosure." Id. (citations omitted).

9. Information included in a drug application often consists of trade secrets, and federal law requires such applications to remain confidential. See id. at 667 n.7 (citing 21 C.F.R. § 314.430(b)-(d)). As such, a party's confidential processes, chemical formulas and specifications, and research information should be sealed. Gabapentin, 312 F. Supp. 2d at 667-68.

**III. Clearly Defined and Serious Injury Would Result if the Relief Sought Is Not Granted**

**A. Findings of Fact**

10. The Confidential Information consists of NDA information and proprietary information regarding business relationships and the formulation, development and manufacture of the drug products that the parties consider to be confidential and proprietary. This information is otherwise unavailable to third parties. For these reasons, the public disclosure of this information would pose a substantial risk of harm to the parties' legitimate proprietary interests and competitive position.

**B. Conclusions of Law**

11. The district court has discretion to balance the factors for and against access to court documents. See Pansy v. Borough of Stroudsburg, 23 F.3d 772, 781 (3d Cir. 1994).

12. Protection of a party's interest in confidential commercial information, such as a trade secret, is a sufficient threat of irreparable harm, and is clearly defined as a serious injury. See Publicker, 733 F.2d at 1071.

**IV. No Less Restrictive Alternative is Available**

**A. Findings of Fact**

13. Once confidential information is disclosed to the public, it can never again be sealed or maintained as private. Moreover, the request to seal and

redact the Confidential Information is tailored to restrict access only to very specific confidential and proprietary business and technical information.

14. The disclosure of this confidential, proprietary information would pose a financial and competitive risk to the parties. Accordingly, the only way to protect the parties' confidential interests is to seal and redact the identified portions of the Transcripts.

15. Only those portions of the Transcripts from which may be discerned confidential and proprietary information will be sealed and redacted.

#### **B. Conclusions of Law**

16. The sealing of confidential documents and information is an accepted practice in the District of New Jersey. See, e.g., In re Gabapentin Patent Litig., 312 F. Supp. 2d 653 (D.N.J. 2004).

17. Under Local Civil Rule 5.3(c)(2), a party seeking to seal documents must meet the fourth prong that no less restrictive alternative to the relief sought is available. See Securimetrix, Inc. v. Iridian Techs., Inc., 2006 WL 827889, at \*2 (D.N.J. Mar 30, 2006).

18. For all the above reasons, and because the parties' interests in the Confidential Information identified herein outweigh the minimal, if any, public interest in its disclosure, there is good cause to grant the instant Motion to Seal and Redact.

Dated: October 26, 2012

Respectfully submitted,

<p><u>/s/ Liza M. Walsh</u></p> <p>Liza M. Walsh <b>CONNELL FOLEY LLP</b> 85 Livingston Avenue Roseland, NJ 07068 Phone: (973) 535-0500 Facsimile: (973) 535-9217</p> <p><i>Attorneys for Plaintiffs GlaxoSmithKline PLC, GlaxoSmithKline, LLC, SmithKline Beecham Limited, Glaxo Group Limited, Pfizer, Inc. and Encysive Pharmaceuticals, Inc.</i></p> <p>Robert J. Gunther, Jr. Christopher R. Noyes <b>WILMER CUTLER PICKERING HALE AND DORR LLP</b> 399 Park Avenue New York, NY 10022 Phone: (212) 230-8800 Facsimile: (212) 230-8888</p> <p>Lisa J. Pirozzolo Vinita Ferrera <b>WILMER CUTLER PICKERING HALE AND DORR LLP</b> 60 State Street Boston, MA 02109 Phone: (617) 526-6000 Facsimile: (617) 526-5000</p> <p><i>Attorneys for Plaintiffs GlaxoSmithKline PLC, GlaxoSmithKline, LLC, SmithKline Beecham Limited, and Glaxo Group</i></p>	<p><u>/s/ Arnold B. Calmann</u></p> <p>Arnold B. Calmann Jeffrey S. Soos Katherine A. Escanlar <b>SAIBER LLC</b> One Gateway Center, 10<sup>th</sup> Floor Newark, NJ 07102-5311 Phone: (973) 622-3333 Facsimile: (973) 622-3349 abc@saiber.com jsoos@saiber.com kescanlar@saiber.com</p> <p>Jeffrey S. Ward Wendy M. Ward Shane A. Brunner <b>MERCHANT &amp; GOULD PC</b> 10 East Doty Street, Suite 600 Madison, WI 53703 (608) 280-6750 (telephone) (612) 332-9081 (facsimile)</p> <p><i>Attorneys for Defendants Hikma Pharmaceutical Co., Ltd. and West-Ward Pharmaceutical Corp.</i></p>
---	--

<i>Limited</i>  Martin L. Katz <b>WOOD PHILLIPS</b> 500 West Madison Street, Suite 3800 Chicago, IL 60661-2511  <i>Attorneys for Plaintiffs Pfizer, Inc. and Encysive Pharmaceuticals, Inc.</i>	
--	--